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Agilent Technologies

Rotating Bottle Apparatus Operator's Manual

P/N 70-9021
November 2010
Revision G

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First Edition (November 2010)
Rotating Bottle Apparatus Operator's Manual
Part Number 70-9021 Revision G
Printed in the United States of America

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Chapter 1 Safety Practices and Hazards

The Rotating Bottle Apparatus has been carefully designed so that when used properly you have an accurate, fast, flexible, and safe instrument.

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

Operation of a Rotating Bottle Apparatus involves the use of solid dosage forms and aqueous liquids. Unskilled, improper, or careless use of this instrument can create shock hazards, fire hazards, or other hazards which can cause death, serious injury to personnel, or severe damage to equipment and property.

Information on safety practices is provided with your instrument and operation manuals. Before using your instrument or accessories, you must thoroughly read these safety practices.

Observe all relevant safety practices at all times.

Electrical Hazards

The Rotating Bottle Apparatus contains electrical circuits, devices, and components operating at dangerous voltages. Contact with these circuits, devices, and components can cause death, serious injury, or painful electric shock.

Panels or covers that are retained by fasteners which require the use of a tool for removal may be opened only by Varian-trained, Varian-qualified, or Varian-authorized service engineers. Consult the manuals or product labels supplied with the Rotating Bottle Apparatus to determine which parts are operator-accessible.

Application of the wrong supply voltage, connection of the instrument to an incorrectly wired supply outlet, or lack of proper electrical grounding can create a fire hazard or a potentially serious shock hazard and could seriously damage the instrument and any attached ancillary equipment.

Always use a three-wire outlet with ground connection which is adequately rated for the load. The installation must comply with local, state, and federal safety regulations.

Do not connect the instrument to the main power supply until you have made sure that the operating voltage is correctly set for the main power supply in the specific outlet in your laboratory to which the equipment will be connected.

Other

Other specific warnings and cautions appear in the manuals where appropriate and detail the specific hazard, describe how to avoid it, and specify the possible consequences of not heeding the warning or caution.

Warning

A 'Warning' message appears in the manual when failure to observe instructions or precautions could result in death or injury. Symbols depicting the nature of the specific hazard are also placed alongside warnings.

These symbols may be used on warning labels attached to the instrument. When you see one of these symbols you must refer to the relevant operation or service manual for the correct procedure referred to by that warning label.

The meaning of the symbols that appear alongside warnings in this manual are as follows:

Electrical shock

Pinch point

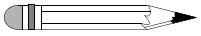
Caution
Refer to accompanying documents

Read all warnings and cautions carefully and observe them at all times.

Caution

A 'Caution' message appears in the manual when failure to observe instructions could result in damage to equipment (Varian supplied and / or other associated equipment).

A 'Note' appears in the manual to give advice or information.



Information Symbols

I	Switches main power on
0	Switches main power off
	Indicates single-phase alternating current
	Indicates the product complies with the requirements of one or more European Union (EU) directives
	Indicates specific equipment meets consensus-based standards of safety to provide assurance, required by OSHA, that these products are safe for use in the workplace for North America
	Indicates that this product must not be disposed of as unsorted municipal waste (see "WEEE Directive" on page 10)

General

CE Compliant Products

The Rotating Bottle Apparatus has been designed to comply with the requirements of the Electro-magnetic Compatibility (EMC) Directive and the Low Voltage Directive (LVD) of the EU.

Varian, Inc. has confirmed that each product complies with the relevant directives by testing a prototype against the prescribed European Norm (EN) standards.

Proof that a product complies with the directives is indicated by:

- the CE marking appearing on the rear of the product.
- the documentation package that accompanies the product containing a copy of the declaration of conformity. This declaration is the legal declaration by Varian, Inc. that the product complies with the directives and also shows the EN standards to which the product was tested to demonstrate compliance. The declaration of conformity is signed by the representative of the manufacturing plant.

cTUVus - U.S. and Canadian Product Approvals

The Rotating Bottle Apparatus has been designed to comply with North American safety requirements.

These products have been tested and certified for the North American market by TUV Rheinland of North America, Inc. The TUVus mark signifies that these products have been tested to U.S. standards and certified for the U.S. market. The cTUV mark signifies that these products have been tested to Canadian standards and certified for the Canadian market. When the two marks are coupled, the cTUVus mark signifies that these products have been tested to standards and certified for both markets.

WEEE Directive

All Varian products that are subject to the WEEE directive shipped after August 13, 2005 are compliant with the WEEE marking requirements. Such products are marked with the "crossed out wheelie bin" WEEE symbol shown on page 8 in accordance with European Standard EN 50419.

This symbol on the product or on its packaging indicates that this product must not be disposed of as unsorted municipal waste. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment.

For more information on collection, reuse, and recycling systems, please contact your local/regional waste administration, your local distributor, or Varian, Inc.

Chapter 2 Introduction

The Rotating Bottle Apparatus is designed for release rate testing of tablets or capsules. Manual changing of media during a test simulates a dosage passing through a pH gradient.

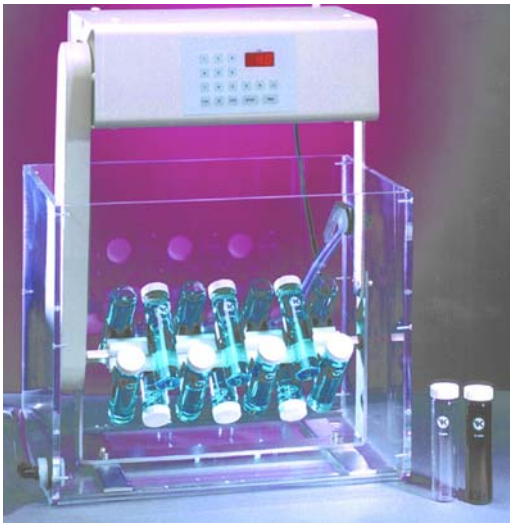
The Rotating Bottle Apparatus includes the following items:

- One system drive with easy-to-read digital display
- One clear acrylic water bath, 19 x 12.7 x 15.3 inches, with VK 750D Heater / Circulator or one clear acrylic water bath, 24 x 12 x 12 inches, for use with an immersion circulator
- One stainless steel drive bar with 14 positions
- 20 standard 100 mL test bottles with caps
- Five decant caps with 40-mesh screen

Warning

The Rotating Bottle Apparatus contains electrical circuits, devices, and components operating at dangerous voltages. Contact with these circuits, devices, and components can cause death, serious injury, or painful electric shock.

FIGURE 1. Rotating Bottle Apparatus

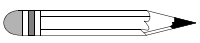


Caution

Panels or covers that are retained by fasteners which require the use of a tool for removal may be opened only by Varian-trained, Varian-qualified, or Varian-authorized service engineers.

Conventions Used in this Manual

- Items you are asked to press are in bold. For example, "press **H** on the keypad".



Note

Remember to return the warranty card supplied with this manual. Completing and returning the card ensures your right to protection under the terms and conditions of your warranty. It also enables us to better assist you in the event of any problems. Additionally, it guarantees you will be informed of any issues that arise concerning your equipment, such as upgrades, retrofits, or regulatory changes.

Chapter 3 Installation and Setup

Warning

Keep your hands clear of the apparatus as it rotates.

Unpacking Your Equipment

Step 1. Open each carton and check the contents for damage which may have occurred during shipping. Shipping damage rarely occurs, but if it does contact both the carrier who delivered the instruments and the Dissolution Systems Service Department. Though claims for damage should be filed with the carrier, we can help you file a claim.

Step 2. Carefully remove the Rotating Bottle Apparatus from its shipping carton. Hold the unit firmly to prevent it from dropping.

Warning

Hold the apparatus only by the base. To avoid damage, do not hold the apparatus by the drive unit.

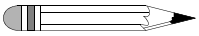
Step 3. Check for items which may have come loose during shipping. Be sure to remove all parts before discarding or storing the packaging.

Step 4. Place the unit on a clean, dry, level section of the bench top or table. At least four inches (10 cm) of space should be open at the rear and on both sides of the instrument.

Warning

The electrical connection at the back of the apparatus is the primary disconnect for the instrument. The apparatus should be positioned to allow accessibility to the power cord for easy disconnection.

Setting up the Water Bath and VK 750D



Note

If your equipment is not supplied with a VK 750D, attach the heater / circulator according to the manufacturer instructions.

To connect the VK 750D Heater / Circulator to the water bath, complete the following steps:

Step 1. Ensure the VK 750D is turned off.

Step 2. Locate the two pieces of plastic tubing and the four stainless steel tubing clamps included in the VK 750D tubing kit.

Step 3. Slip one end of each piece of tubing over the barbed 90-degree angle adapters in the inlet and outlet bulkhead fittings. The inlet fitting is the higher of the two fittings. It should have a perforated deflector screen attached on the inside of the water bath. Slide the tubing as far up on the adapter as possible.

Step 4. Slip a tubing clamp over the free end of each of the pieces of tubing, then slide them over the barbed angle adapters. Tighten each clamp by turning the screw.

Caution

Do not over-tighten the tubing clamps. Damage to the tubing could result.

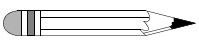
Step 5. Slip the other pair of tubing clamps over the free ends of each piece of tubing and insert the tubing ends onto the inlet and outlet connectors on the rear of the VK 750D. Ensure the tubing connected to the water bath inlet attaches to the VK 750D rear panel connector labeled OUTLET and the tubing connected to the water bath outlet attaches to the VK 750D rear panel connector labeled INLET.

Step 6. Slide the clamps up over the inlet and outlet connectors, then tighten. To avoid damage to the tubing, do not overtighten.

Step 7. Double check all connections.

Step 8. Fill the water bath with ultrapure water.

Note



If possible, preheat the water to speed achievement of the desired water bath temperature. Use purified water whenever possible to minimize scale and mineral buildup. Algaecides may be used to inhibit algae and bacteria growth. Check the label to ensure the formulation is compatible with the plastic materials used in the water bath construction.

Initial Power Up

Power Cord Connections

Step 1. Ensure the Rotating Bottle Apparatus is turned off.

Warning

Before plugging the Rotating Bottle Apparatus into any power outlet, ensure the instrument is properly configured for the voltage provided. Check the serial number tag on the rear panel of the instrument to confirm the voltage requirement.

The electrical connection at the back of the apparatus is the primary disconnect for the instrument.

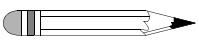
Step 2. Connect power cords to the receptacles at the rear of the Rotating Bottle Apparatus and the VK 750D.

Step 3. Plug the cords into electrical outlets of the appropriate voltage.

Powering Up the VK 750D Heater / Circulator

Turn on the VK 750D. Flow should begin immediately and the unit should operate quietly with a low "hum". Bubbles may appear at the water bath inlet as air is expelled from the system. After a few minutes flow into the water bath should be smooth and steady. If not, stop the system and prime it as described in the *VK 750D Heater / Circulator Operator's Manual.*

Note



Make a final check for leaks. Allow the heater / circulator to run for five minutes, then check the water bath, tubing, connectors, and the bench area immediately surrounding the apparatus. If any water leaks are seen, turn off the power immediately and remove the power cord. Locate and fix the source of the leak before proceeding.

Powering Up the Rotating Bottle Apparatus

Turn on the Rotating Bottle Apparatus. The red LED on the front panel illuminates. If it does not, ensure the unit is securely plugged in and there is power at the outlet. If the unit still fails to respond, see "Troubleshooting" on page 27 or call the Dissolution Systems Service Department.

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Chapter 4 Operation

Warning

Keep fingers and loose clothing away from the lower end of the drive belt assembly.

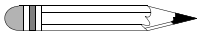
The procedure as described in NF XIV is not an official method, but is suggested as a suitable test that could be helpful in assuring product uniformity of timed-release tablets and capsules. See General Tests, “Timed-Release Tablets and Capsules–In Vitro Test Procedure,” pages 985-986, NF XIV, July 1, 1975.

To operate the Rotating Bottle Apparatus, complete the following steps:

Step 1. Add tablets or capsules and extracting fluid to the standard test bottles.

Step 2. Secure the standard caps on the bottles.

Step 3. Snap the bottles into the clips.



Note

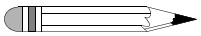
For even speed control, the bottles should be distributed in parallel pairs on opposite sides of the shaft.

Step 4. Center each bottle within the clip.

Step 5. Carefully place the apparatus in the water bath.

Step 6. Turn on the Rotating Bottle Apparatus.

Step 7. Press **C** on the keypad to select the speed and enter the desired rotation speed (between 10 RPM and 60 RPM).
Optionally, press **B** on the keypad to toggle between 30 RPM and 40 RPM.



Note

Key A on the keypad is inactive.

Step 8. Press **RUN** to begin rotation of the bottles.

Step 9. At the appropriate sampling time, press **STOP**. The apparatus pauses and the bottles stop rotating.

Step 10. Remove the bottles from the clips.

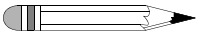
Step 11. Replace the standard caps with 40-mesh decant screen caps.

Step 12. Decant, retaining the residue.

Step 13. Add extracting fluid to the residue.

Step 14. Replace the 40-mesh decant screen caps with the standard caps. Ensure the caps are secured tightly.

Step 15. Snap the bottles into the clips.



Note

For even speed control, the bottles should be distributed in parallel pairs on opposite sides of the shaft.

Step 16. Center each bottle within the clip.

Step 17. Press **RUN** to continue the test.

Step 18. Repeat steps 9 - 17 as required by the test procedure.

Step 19. When the test is complete, press **STOP**.

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Chapter 5 Maintenance and Troubleshooting

Periodic Maintenance

Warning

The Rotating Bottle Apparatus contains electrical circuits, devices, and components operating at dangerous voltages. Contact with these circuits, devices, and components can cause death, serious injury, or painful electric shock.

Panels or covers that are retained by fasteners which require the use of a tool for removal may be opened only by Varian-trained, Varian-qualified, or Varian-authorized service engineers.

Periodic maintenance intervals may vary depending on frequency of instrument usage.

Daily Maintenance

- Immediately wipe all spills or errant materials from the exterior of the instrument or any exposed part using a clean cloth and plain water.
- Carefully wash the bottles and caps after each use.

Weekly Maintenance

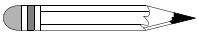
See "Water Bath / Acrylic Care" on page 25 as applicable for additional information on proper maintenance of your equipment.

- Inspect the water bath and heater / circulator tubing for algae or other materials. If algae is present, change the bath water and add an algaecide.
- If you use a water bath algaecide or clear bath product, ensure it is compatible with PETG and acrylic.

Monthly Maintenance

See "Water Bath / Acrylic Care" on page 25 as applicable for additional information on proper maintenance of your equipment.

- Clean the outside of the apparatus with a damp cloth.
- Drain the water from the water bath and clean the bath thoroughly. Refill the water bath and add an algaecide.
- It is recommended that the water bath temperature probe jack is checked for surface corrosion and wiped clean with a soft cloth or nonabrasive pad every one to three months.



Note

Depending on the frequency of use, it may be necessary to complete this maintenance procedure more often.

Annual Maintenance

- Inspect all electrical connections for corrosion and damage.
- Clean the outside of the apparatus with a damp cloth.
- Check the belt tension—total deflection should not exceed 1/2 inch (1.3 cm).

Water Bath / Acrylic Care

Caution

Do not use cleaning compounds containing ammonia or abrasive cleaners on your water bath.

The water bath supplied with the Rotating Bottle Apparatus should be maintenance free except for an occasional cleaning. If you use a water bath algaecide or clear bath product, ensure it is compatible with PETG and acrylic. The flow paths in the immersion circulator are primarily stainless steel and should tolerate most clear bath formulations. Check with the product manufacturer to be sure the product is safe for your water bath.

1. All of our water baths are fabricated entirely of commercial grade acrylic. When using them with corrosive materials such as hydrochloric acid or media containing salts, be sure to rinse them thoroughly with deionized water immediately after each use, and dry thoroughly with a soft towel or cloth.

2. Do not clean with abrasive cleansers or cloths. Use deionized water whenever possible. If you must use a cleanser or solvent, be sure that it is as mild as possible, non-abrasive, and fully compatible with PETG and acrylic before use. If in doubt, call the service department for advice before proceeding.

3. Do not use ammonia, window-cleaning sprays, kitchen scouring compounds, or solvents such as acetone, gasoline, benzene, alcohol, carbon tetrachloride, or lacquer thinner. These can scratch the material's surface and / or weaken it causing small surface cracks called "crazing".

4. Our recommendations include but are not limited to the following:
   - Hot water:< 150 °F
   - Vinegar (5% Glacial Acetic Acid)
   - Ethyl alcohol: maximum 10%
   - Isopropyl alcohol: maximum 25%

Fuse Replacement

Warning

The Rotating Bottle Apparatus contains electrical circuits, devices, and components operating at dangerous voltages. Contact with these circuits, devices, and components can cause death, serious injury, or painful electric shock.

Panels or covers that are retained by fasteners which require the use of a tool for removal may be opened only by Varian-trained, Varian-qualified, or Varian-authorized service engineers.

Follow these steps to replace the fuse:

Step 1. Before checking or attempting to replace a fuse, remove the power cord from the unit.

Step 2. Press the release tab on the fuse holder located in the power entry module with the blade of a small screwdriver or equivalent.

Step 3. Upon release, slide the holder out of the AC power entry module.

Step 4. Remove the old fuses and insert the new fuses.

Step 5. Slide the holder back into the power entry module and push until it locks into place.

Step 6. Replace the power cord.

Warning

Never replace a fuse with one of a higher amperage rating. Doing so may compromise the safety margin and could result in damage to the instrument or personal injury.

Troubleshooting

The Dissolution Systems Service Department can assist you if you experience problems or have questions concerning your Rotating Bottle Apparatus. Many problems can be traced to simple sources and are easily solved.

Following is a troubleshooting guide which may help you. The Dissolution Systems Service Department can be reached at 800.229.1108 (inside the US) or 919.677.1108 (outside the US). Optionally, you can send a fax to 919.677.1138. You can also e-mail the Dissolution Systems Service Department at dissolution.service@varianinc.com.

Symptom	Probable Cause	Possible Solution
There is no power to the apparatus.	The fuses are blown (open).	Replace the fuses in the power entry module. See "Fuse Replacement" on page 26.
	There is no power at the electrical outlet.	Verify that the outlet has power going to it.
	The power cord is damaged or is not plugged in.	Check the power cord for abrasion and proper connection. Replace if necessary.
	The power entry module is faulty.	Check the module to ensure proper voltage delivery. Contact the Dissolution Systems Service Department for assistance.

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Chapter 6 Service and Warranty

The warranty is provided by Varian, Inc. or one of its authorized representatives.

Service and Warranty Information

Varian dissolution products carry a one-year warranty on parts and labor. The Dissolution Systems Service Department (or one of its representatives) will, at its option, either repair or replace any mechanical and electrical components in your instrument which prove to be defective. During the first year of warranty coverage, there is no charge for the labor to repair your unit. The Dissolution Systems Service Department (or one of its representatives) will determine the best site to repair the unit, either onsite or returned to Varian, Inc. Any onsite warranty services are provided only at the initial installation point. Installation and onsite warranty services are available only in Dissolution Systems service travel areas.

Exclusions and Limitations

Excluded from this warranty are expendable or consumable items such as, but not limited to, paddles, baskets, vessels, and acrylic water baths. Also excluded are defects from improper or inadequate maintenance by the customer, user-induced chemical action or contamination, unauthorized modification or misuse, and improper site preparation and maintenance.

Operation of software is not warranted to be uninterrupted or error-free.

Obtaining Warranty Service

To obtain warranty service in the United States, contact the Dissolution Systems Service Department at 800.229.1108 to obtain authorization to return units for repair. At the option of the customer, onsite warranty service is available, but travel charges may be incurred. The customer should prepay all shipping charges for products returned to the Dissolution Systems Service Department (unless otherwise authorized), and Varian, Inc. will pay all charges for return to the customer.

Warranty Limitations

Varian, Inc. makes no other warranty, either express or implied, with respect to this product. Specifically disclaimed are any implied warranties of merchantability and fitness for a particular use. In no event will Varian, Inc. be liable for any indirect, incidental, or consequential damages arising from the use of this product. This warranty gives you specific legal rights which may vary from state to state or province to province, so you may have other rights and some of these exclusions may not apply to you.

Exclusive Remedies

The remedies provided herein are the customer's sole and exclusive remedies. In no event shall Varian, Inc. or its representatives be liable for any direct, indirect, special, incidental, or consequential damages, whether based on contract, tort, or any other legal theory. Some states or provinces do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

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Tell Us How We Are Doing

We listen to our customers. We work hard to make our technical documentation user friendly, and to make the information in our manuals easy to retrieve and use. We'd like you to tell us the kinds of additional information you'd find helpful in our documentation. Your feedback will be carefully considered when we prepare future editions of this manual.

This manual should contain the following additional information:

The most useful thing about this book is:

This manual would be more helpful if:

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